Does the New Intellectual Property Rights Regime Impede Innovation in Developing Countries: A Case Study of The Indian Pharmaceutical Industry.

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1. Introduction to Intellectual Property Rights

This paper starts with a simple and brief introduction of **Intellectual Property Rights.** Intellectual property gives certain **right** to some individual to **exclude others** from the use of specific **intangible creations/innovations** for a certain **period of time**. These creations take the form of tangible products. The Law gives protection to the intangible creations like ideas, technical solutions. This implies that the owner of a patent can prevent the manufacture, use or sale of the patented product in the countries where the patent has been registered. This explains why intellectual property rights may have a direct and substantial impact on industry and trade

Intellectual property rights include the following categories:

- Copyright and related rights
- Trademarks
- Geographical indications
- Industrial designs
- Patents
- Layout designs of integrated circuits
- Trade secrets
- Breeders' rights
- Utility models.

The relevance and importance of different categories of IPRs varies from country to country. It depends upon:

- The level of technological and economic development,
- Different degrees of R&D intensity
- Rate and nature of innovative activities
- Type of goods and services it produces.

Technological developments which can actually be categorized as **`inventions'** are rather rare in developing countries; In most cases, patents granted there belong to foreign companies and only a few to nationals.

2. TRIPS-A New Regime

General Agreement on Tariffs and Trade (**GATT**) negotiations on 1 January 1995 introduced the New Intellectual Property Right **(IPR)** regime under **Trade Related Aspects of Intellectual Property Rights** (**TRIPS)** . It required the developing countries to amend their existing IPR regimes and adopt ones similar to those prevailing in the industrialized countries. The TRIPS Agreement requires the member countries to recognize **seven** forms of IPRs; i.e. **Copyrights, Trademarks, Geographical Indications, Industrial Designs, Patents, Layout designs of integrated circuits, and Trade Secrets.** IPR included the Breeders' Rights and Utility models but the new regime under TRIPS excludes them.

TRIPS permits developing countries such as India a transition period of five years to implement the provisions of TRIPS. In addition, if a country did not provide product patent protection in any field when TRIPS came into force, then additional 5 years is also given to them. Even though the Developing countries such as India had time till 1 January 2005 to introduce full product patents protection for pharmaceuticals and agricultural chemicals, they were required to introduce 'mail box' (receiving and holding

product patent applications in the fields of pharmaceuticals) and 'exclusive marketing rights' provision from 1 January 1995.

The **main provisions** relating to Patents in TRIPS are as follows:

- Patents shall be available for any invention, whether a product or process, in all fields of technology without discrimination, where those inventions meet the standard substantive criteria for patentability —novelty, inventive step and industrial applicability.
- The available term of protection must expire no earlier than 20 years from the date of filing the patent application.
- The Patent Owner has the Right to prevent unauthorized persons from using the patented process and making, using, offering for sale, or importing the patented product or a product obtained directly by the patented process.
- The Agreement allows limited exceptions to be made by Members provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent. One such case is the '**Bolar Provision'**,in which the generic producers of patented products, are permitted without authorization and prior to the expiry of the patent term, to use a patented invention for research purposes, so that they can seek regulatory approval from public health authorities for the marketing of their generic version as soon as the patent expires.
- The Agreement also allows Members to authorize use by third parties (**compulsory licenses**) or for public non-commercial purposes (**government use**) without the authorization of the patent owner.
- In case of Infringements, the burden of proof will be on the alleged infringer rather than on the right holder. [*]

3. TRIPS-developed vs. developing countries

Developed countries supported the New IPR regime under TRIPS because, Technological advancements and developments in developing countries was going at a fast pace mainly because of technology diffusion and spillovers from the developed countries.This was attributed to the open technological and scientific system. So there was a relative loss of competitiveness. Moreover, the developed countries who were more into R&D saw a steady rise in the expenditure incurred on R&D purposes; but comparatively less revenue earned due to weaker protection of IPR as in the developing countries. So,I f they could get a stronger protection, it would recoup their costs and give them an incentive to innovate further.

The main point of argument of the developing countries with regard to the weak protection of IPRs in chemicals, foodstuffs and pharmaceuticals can be attributed to the fact that it serves as an instrument to avoid restrictions in **"the supply of essential products"**, with the implicit assumption being that technological innovation should be considered as a public good and not a private capital good. Other points of concern included the exploitation of market power by foreign companies - wiping out of the domestic firms by MNCs and the impact of protection on domestic prices mainly leading to a spiraling of prices.

[*] Provisions incorporated from website

http://www.wto.org/English/tratop_e/trips_e/pharma_ato186_e.htm

In this regard, the words of **Indira Gandhi**, spoken at the **World Health Assembly in May 1982** is worth quoting:

"The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death."

UNCTAD also recommended in 1975 that pharmaceuticals should be made available to developing countries at a marginal cost. This meant that extensive R&D to be performed for new drugs, which are tailored to the needs of developing countries, i.e., which addresses the general tropical diseases of the developing countries and attacks the population in masses.

Yet, some of the possible reasons for the developing countries to accept the stronger IPR protection may be attributed to the following reasons:

- Decreasing private capital flows to developing countries,
- Negative experiences with the regulatory approach.
- Ongoing "technological revolution"
- Reasonable amount of respect for IPRs is fundamental for stimulating technological change.

[*]The **costs and benefits** of strengthening the IPR system befalling a **developing country** can be discussed as under:

Among the **COSTS** are,

- **Administrative and enforcement costs** associated with the reform, which are not trivial;
- The **increased royalty payments**
- The **costs of economic displacement of "pirates",** which involves two **social** costs, namely displacing/wiping out of the companies/pirate firm and the rise in unemployment level (as the factors of production displaced from the affected industry would not find employment in the other sectors of the economy.);
- **Loss in consumer surplus generated by the anticompetitive aspect of such measures** (there would be significant increase in prices due to increased market power which enables the seller to reduce output and raise prices, and driving a larger wedge between price and marginal cost , increasing static welfare losses. Evidence suggests that patents "in most cases do not prevent imitation and thus may not slow down diffusion to any great extent". IPRs may affect learning economies and increase entry barriers. Brand Loyalty will be a more effective barrier to entry under a strengthened IPR system).

The main **BENEFITS** are,

- **Cost savings derived from additional domestic R&D** and the disclosure of new knowledge (the qualitative implications of IPRs, i.e. the degree to which they foster genuine innovation as opposed to mere imitation);
- Positive contributions to **global technological dynamism** (inventors in the industrialized areas of the world may need some special incentive to concentrate their talents on products of special utility to underdeveloped areas);
- Benefits from **additional technology transfers** (technology owners do not have an incentive to transfer their proprietary knowledge to countries with weak IPR systems, in view of the potential for "piracy");

[*] World Bank Discussion Papers (112)(2001)

- More **capital formation in knowledge intensive sectors** (composition of foreign direct investment will increase in the developing country)

4. The India Patents Act 1970

The Patent Regime in India can broadly be classified under the following three heads:

- **Patents and Designs Act of 1911**, which effectively had a product patent regime in drugs and medicines.
- **After 1972,** the Patents and Design Act, 1911 was replaced by the **Patents Act, 1970. D**rug product patent protection was abolished and process patents came into being. India became a major producer and a source of low cost but high quality drugs for the entire world.
- **From 1 January 2005**, post **TRIPS**, drug producer patent protection has again been introduced in India.

With respect to process patents, the provisions related to 'License of Rights', "compulsory license", "working of patent within 3 years of sealing date", "burden of proof in case of patent infringement" further limited the scope of protection substantially. The abolition of pharmaceutical product patent protection in 1972 paved the way to achieve an independent Indian pharmaceutical industryGoing by the statistics, the Indian Patents Act was a **'success'**. The number of supplying firms increased from 2,237 licensed drug manufacturers in 1969-70 to an estimated 16,000 producers in 1992-93. The production of drug formulations grew at an average annual rate of 14.4 percent between 1980-81 and 1992-93; the negative balance of trade in bulk drugs and drug formulation that prevailed throughout the 1970s and 1980s was turned into a trade surplus by 1990. [*]

The period 1970-2004 saw a **declining market share of Multi National Corporations** (MNCs) in India. In 1970, Indian owned firms held a share of only 10-20 percent of the total pharmacy market, MNCs accounted for the remaining 80-90 percent. By 1980, Indian firms and MNCs had an equal share of about 50 percent; by 1993, Indian firms had raised their share to 61 percent and by 2004,the share of Indian firms has increased to 75%. The relative decline of MNCs in the Indian pharmacy market has been attributed to various factors, in addition to the abolition of product patent protection through the Indian Patents Act.

[*] Fink Carsten," How stronger Patent Protection in India Might Affect the behavior of Transnational Pharmaceutical Industries"

Table 1
Market shares of MNCs and Indian Companies in the Pharmaceutical Industry

Year	Multi National Companies	Indian Companies
1952	38	62
1970	68	32
1978	60	40
1980	50	50
1991	40	60
1998	32	68
2004	23	77

Source: , Chaudhuri Sudip Table 2.2: page-18

The imitation and production of drugs protected by patents in other countries by reverse engineering was the key to success for Indian firms. This has been possible due to highly developed chemical infrastructure and good process skills of the Indian firms. Thus it was possible for Indian firms to introduce the copied brands in the Indian market soon after the world introduction of these drugs at affordable prices, thus making it a competitive market in the world. Moreover, The Indian Patent Act of 1970 providing only seven years of process patent protection for pharmaceuticals, and rigid price control of the government posed a huge opportunity for the domestic industry to produce generics.

The transition of the Indian Pharmaceuticals Industry from an import dependant one in 1950's to a self sufficient supplier and exporter of high quality drugs at affordable prices can be attributed to the process patent regime.

5. India's Patent Policy and TRIPS

The TRIPs Agreement came into effect on January 1, 1995 with the provision that India must have a regime that grants pharmaceutical product patents by 2005. Failure to meet TRIPs requirements would jeopardize India's market access rights and other benefits under the WTO.

The philosophy of India's Patent Act of 1970, supporting innovation as a public rather than private good, varied significantly from the framework being established under TRIPs. Though it covered the public interest angle, it also helped the growth of industry.
The type of patent system that India established was clearly against the global IP regime promoted by the US. The main objection of the US is to the provision in India's patent law that allows for process but not product patents in the area of food, drug or medicine. This can be traced to the reason that the costs for developing a new drug/chemical entity(NCE) is very high and the costs for developing processes for manufacturing a new drug is low. So, without patents, it may be possible to imitate the new products thereby limiting the innovators ability to recoup the R&D costs. The United States terms the activities of India to find alternative processes by reverse engineering as "piracy". According to the US, Indian firms are copying technology developed by advanced nations. This is leading to large-scale losses for the US. The Pharmaceutical industry in the US especially *Phrma*, the association that represents US based pharmaceutical companies has been quite vocal on this issue.

Table 2
Summary of Indian Patents Act, 1970 and TRIPS 2005

Indian Patent Act	TRIPS
Only process, not product patents in food, chemicals and pharmaceuticals	Process and product patents in almost all fields.
Tenure of patents-14 years, 5-7 in chemicals, drugs	Tenure of patents-20 years
Compulsory licensing and license of right exercised	Provision of compulsory licensing but no license of right.
Government allowed to use patented invention to prevent scarcity in emergency.	Very limited scope for governments to use patented inventions.

These amendments in the Patent Act so as to comply with TRIPS may foster major changes in the Indian Pharmaceutical sector. Indian companies will not be legally able to produce generic versions of drugs currently protected by patents. Since India is a haven for generic production of drugs, there will certainly be a negative impact on the domestic growth and production. From the consumer point of view, some of the main impacts will be the unavailability of cheap generic drugs before the 20-year period of protection elapses and the generally higher prices of drugs. Generally increased protection implies increased R&D, but it necessarily does not imply preferential investment in medicines needed by the poor.

6. The Pharmaceutical Sector in India

The Indian Pharmaceutical industry is the pre-eminent sector in India, in terms of scientific and technological developments. It meets about 70% of India's demand for bulk drugs, drug intermediates, chemicals, and pharmaceutical formulations in the form of tablets, capsules and orals. Some Important facts about the Pharmaceutical Industry in India worth mentioning are:

- Size of India's pharmaceutical market is US$4.9 billion (2003) in sales and US $3.8 billion in exports. This constitutes about 1% of the global pharmaceutical sales and about 10% of the total generics market in the world. In value terms, India is the 14th largest market in the world and continues to show satisfactory progress in terms of infrastructure development, technology base and product use.
- In volume terms, India's share is around 8% and is the 4th largest after USA, Japan, and China and in value terms it is 13th largest.
- India is among the top 5 bulk drugs manufacturers of the world. India has the largest number of US Food and Drug Administration (FDA) approved manufacturing facilities outside USA. It also has the largest number of Drug Master Files (DMFs) filed which gives it access to the high growth generic bulk drugs market.
- India exported drugs worth US$3.2 billion to more than 65 countries. India is the 14th largest exporter of drugs in the world.
- The Indian pharmaceutical market has been forecast to grow to as much as US$ 25 billion by 2010 as per Organisation of Pharmaceutical Producers of India (OPPI) estimates. However, Espicom's market projections forecast more modest but stable annual market growth of around 7.2 per cent, putting the market at US$ 11.6 billion by 2009.
- The market has been growing between 6-8 per cent over the last two years, primarily driven by new launches and to some extent by volumes.

In the last two years, more than 3,900 new products (largely branded generics) have been launched in India, contributing about US$ 355.6 million (million) worth of market value. While the Indian pharmaceuticals majors launched more than ten products per year, global MNCs averaged one or two annually. In 2005, Indian companies controlled 70 per cent of the domestic market. [*]

The phenomenal progress made by the industry over the years is depicted in Tables 3 & 4.

Table 3
Temporal Progress Of The Pharmaceuticals Industry

Year	**Status**	
1950s	Formulations	Mostly imported MNC dominance
1960s	Formulations	Domestic endeavor on imported bulk drugs
1970s	Formulations Bulk drugs	Some imports. Indigenous manufacture by domestic companies
1980s	Formulations Bulk drugs	Marginal imports (<5%) Significant indigenous manufacture (based on domestic R&D)
1990s	Formulations Bulk drugs	Significant exports, minimal imports (< 2%) Self reliant (exports > imports)

Source-PRDC Reports

The table above clearly depicts the growth of the Indian Pharmaceutical Industry from an import dominated one to one which was self-reliant.

[*] Chaudhuri Sudip (2005) Box 2.1 page-51 and www.ibef.org

Table 4
Growth of Pharmaceutical Industry (Rs.Crores):

		1965-66	1980-81	1994-95	1997-98	2001-2002	2002-2003	2005-2006
Capital Investment		140	500	1200	1840	2150	2500.00	3200.00
Production	**Formulations**	150	1200	7935	12068	13878	15960.00	18750.00
	Bulk Drugs	18	240	1518	2623	3148	3777.00	5113.00
Import		8.20	112.54		2868.00	3128.00	3441.00	4267.00
Export		3.05	46.38	2184	5353.00	5959.00	6631.00	7980.00
R & D Expenditure		3	14.75	140	220.00	260.00	320.00	560.00

Source-PRDC Reports

Overall scenario as deduced from this chart is not very encouraging in terms of all the vital parameters like Capital Investment; Production of both Formulations and Bulk Drugs, Import, Export and R&D Expenditure post TRIPS. R&D Expenditure is 6% of sales. If we compare the figures of ’80-81 to ’94-’95 and ’94-’95 to ’05-’06,

On the production side,

From ’80-81 to ’94-95,the increase in formulations has been approximately 6.5 times and for bulk drugs, it is almost 7 times. But the increase from ’94-’95 to ’05-’06 has been 2 and 2.5 respectively for formulations and bulk drugs.

Regarding Exports:

From ’80-’81 to ’94-’95 there has been a 50 times increase but in the later period, i.e, from ’94-’95 to ’05-’06, the increase has merely been by 4 times.

On the R&D front:

From ’80-81 to ’94-95, it has shown a ten times increase but from ’94-’95 to ’05-’06, the increase is not even 4 times.

Table 5
Top Countries Of Exports Of Indian Pharmaceuticals in 2004-2005 (Rs.Crores):

Name of Country	2004-05	Name of Country	2004-05
USA	772	Italy	151
Russia	593	Spain	229
Germany	425	Nepal	223
Hong Kong	556	Sri Lanka	224
Nigeria	558	Japan	220
U.K.	357	Thailand	218
Brazil	363	China	237
Singapore	345	Italy	151
Netherlands	219	Spain	229
Iran	280	Nepal	223
Brazil	363	Sri Lanka	224
Vietnam	241	Japan	220
China	237	Thailand	218
Vietnam	241		

Source-pharmainfo.net

The table above indicates that India still controls a substantial share in the world market with US topping the list. The Indian government-backed Basic Chemicals,

Pharmaceuticals and Cosmetics Export Council, CHEMIXCIL, set an export target of Rs 610,000 million (US$13.46 billion) by 2006-07 and opposed formation of PHARMEXCIL, saying it could adversely affect India's drugs export.

7. Impact of Product Patents On The Pharmaceutical Sector in India

When we are talking about the implications of New IPR Regime on pharmaceuticals, then it is worthwhile to discuss three categories of drugs:

Old drugs-these implies those drugs which are already off patent when the new IPR Regime came into being.
New drugs which had some patent life left when TRIPS came into being: the most prominent example in this group would be the anti retroviral drugs for HIV/AIDS.
Future drugs-these implies those set of drugs which are yet to be researched upon and discovered.

The impact of Product Patent on these aspects have been studied:

7.1 Affordability and Accessibility of Medicines

The impact of TRIPS on pharmaceutical industry in India has been a source of debate especially that related to the accessibility and affordability of medicines. India is a major source of supply of the world's generic medicines; it exports 66.7% of its products to developing countries The prices of drugs in India are in fact much lower than the prices in other countries like Pakistan, U.K. and U.S.A., where product patents are in force. For illustrations Ranitidine is sold by Glaxo in India at Rs. 7.20. The same product is sold by the same company in Pakistan at Rs. 65 and in the U.S.A. at Rs. 545. Similarly, the anti-viral drug Aciclovir costs Rs. 33.75 in India while the same drug is sold in Pakistan at Rs. 363.

Here, I deal with two cases which indicates that post TRIPS, medicines may become unaffordable:

Scenario pertaining to AIDS (Acquired Immuno-Deficiency Syndrome):
AIDS is the most deadly infectious disease in the world today, which currently has no cure. But antiretroviral drugs (ARVs) are available for the virus HIV; which prevent the outbreak of AIDS. These ARVs have changed the very face of the disease from a fatal disease to a more manageable one in the developed countries like USA and Europe, where the people can afford it. But, if we take a look at the developing countries, the scenario is not very encouraging.
Here, the case of Sub Saharan Africa is worth mentioning: GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI), the two pharmaceutical giants involved in the case, between them hold the patents for the three antiretrovirals that make up the most commonly prescribed treatment for AIDS in Africa: AZT and lamivudine (GSK), and nevirapine (BI). A court case had been going on for a year in South Africa, pitting pharmaceutical companies against anti-AIDS campaigners. On 9 December 2003,it ended in the signing of a historic agreement between the two parties, opening the gates for generic anti-AIDS medicine to be made available across sub-Saharan Africa. Under the new agreements, producers of generic medicines will swiftly be granted licences to make and distribute these three compounds, subject to "reasonable" conditions - royalties payable to the patent-holders will not exceed 5% of the net sale price. These licenses will be "voluntary", which saves the pharmaceutical companies the humiliation of having states

issue decrees or pass requisition laws in the form of "compulsory" licenses, and should mean the medicines are made available to patients more quickly. The agreements also provide for the producers of generic medicines to make, export, market and distribute their versions of the compounds in the 47 other countries of sub-Saharan Africa. Generic treatments should be available at $140 per patient per year, when in those days brand name medicines cost $10,400 a year.

Currently, of the 6 million people who urgently need ARV therapy in developing countries to survive, fewer than 8% are receiving it. (WHO and UNAIDS 2003,pp. 3-4). MNCs have been accused of taking advantage of their patent rights to charge exorbitant prices for the AIDS drugs still under patents and depriving the poor in economically backward countries to avail of the treatment available (Dutfield 2003, p.29). Effective antiretroviral (ARV) treatment **(triple therapy-stavudine+lamivudine+nevirapine)** to combat the disease can cost more than US$10,000 (before the introduction of generics by India) annually per patient; At that price, it would cost the developing countries like Kenya and Zambia more than their national income to provide treatment thus making it almost impossible to treat all patients.

Generic competition fueled by Indian production has been largely responsible for reducing the prices of antiretrovirals by as much as 98%.There has been a change in this pricing from September 2000, when Cipla, a generic company from India, offered to sell the triple therapy at US$ 350 (per year). This resulted in a crash down of prices. The originator company had no other way out than to reduce the price in the market so as to stay competitive. The prices scaled down to US $931 by January 2001 and then further down to US$ 727 by March 2001.Since then, other generic companies from India have made their entrance into this ARV market, further pulling down the prices. From April 2003, the triple therapy is available from Hetero at US$ 201 against the originator company's price of US$ 727. (MSF 2003a). The AIDS pandemic has clearly showed the **negative impact of implementing the product patent system.**

The generic production of medicines, both finished and raw materials form have helped in moving the treatment scale up in sub-Saharan Africa, South America, and Southern and Southeast Asia. But, generic production only of older, pre-1995 generic versions of medicines is not enough to satisfy the treatment needs of people in developing countries. Now, when India adopts the new IPR regime, then that will prevent generic competition for newer, more expensive "second-line" AIDS medicines which implies prices of newer "second-line" antiretroviral treatments will simply be out of reach of the people residing in developing countries and requiring them badly. These are precisely the medicines that will be considered for patent protection in India. These medicines include GlaxoSmithKline's Combivir (zidovudine/lamivudine fixed-dose combination), which is widely used in generic form in India and in African countries, Gilead's tenofovir (TDF), Abbott's Kaletra, and other important antiretrovirals. 20-year monopolies will drive up the price of treatment in India and in hundreds of importing countries—the world's source of supply of generic HIV medicines will essentially disappear. A recent case study by a World Bank economist [Chaudhuri, S., et al. "Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India." December 1, 2004 (Working paper)] estimates that the cost to consumers in India alone of India's Patents Act amendments will be untenable.

Anti Leukemia Drug-Gleevec:

Now, let us deal with the life saving anti - leukemia drug Gleevec (Imatinib mesylate). Imatinib mesylate was once knows as STI571 but is now sold by the Swiss Pharmaceutical giant, Novartis as "Gleevec" in the United States and as "Glivec" elsewhere. It is FDA-approved for two rare forms of cancer: chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). Gleevec, caused tremendous public outcry as prices rose in India from Rs.10, 000 to 1.2. lakhs per month due to "exclusive marketing rights" (EMRs) given to Novartis by the government during Nov 11, 2003, which rendered treatment unaffordable for majority of the patients.It is said that the generics companies like Sun, Ranbaxy, Cipla ,Hetero, Torrent, and Emcure were forced to withdraw their generics out of the market when Novartis was given the EMRs- because an EMR gives Novartis the right to be the only company in the country legitimately marketing the drug for a period of time..

The generics companies had even stopped production anticipating that Novartis would receive the product patent. Novartis has taken a legal recourse to stop Indian Companies from making and marketing the copied versions of the drug. Natco Pharma, a Hyderabad based Pharmaceuticals Company, which launched a generic version of Gleevac under the brand `Veenat', had challenged the grant of EMRs to Novartis. According to the Natco Pharma Vice-President, Business Development, Mr Rajeev Nannapaneni, under the provisions of the Indian Patent Act and Rules, exclusive rights can be granted only in respect of patents and applications filed in a convention country after January 1, 1995[*]. "*According to the information available, the applications for patents with respect to Imatinib Mesylate were filed (by Novartis) prior to 1995. In this backdrop Natco feels that grant of rights is not correct, and therefore, feels that it has a strong case for revocation of the exclusive rights,"* he said. He also said *"Granting of exclusive rights to a costly therapy, which prohibits the availability of an equally good medicine at a fraction of the cost, is against humanitarian principles. In effect, implementation of the exclusive rights would make the drug out of reach for thousands of patients who are already on Veenat and consequently, this would mean a death sentence to ill-affordable patients."* This case is currently pending before the Supreme Court.Vice Chairman, Novartis also puts forward his point of social welfare as he says the company had given the anti-cancer drug free to about 3,306 patients and only 45 were actually paying for the medicine. "*On an average, about 30-odd patients enrol for the free cancer drug per week*," he said,

It seems that the government has started intervening in the Novartis' market. The Government has asked Novartis for market-related data on the drug, the pricing and the number of patients who need it. This could be laying the ground for Government intervention if the price is found to be too high and if patients have been denied the drug, an industry representative said.The Government can allow other local companies to produce the same cancer drug and hence bring down its price. The other option before the Centre is to fix the price on the drug through some sort of a price-control, said a patent attorney.Either way, the government will be able to support the present Patent Ordinance and convince Parliament that safeguards are in place to protect the patient.

Subsequently, Novartis had applied for an Indian patent and Natco had filed pre-grant opposition petition before the Controller of Patents & Designs, as provided in the amended Patents Act and Rules. This coupled with reactions from vigilant patients'

[*] Natco to challenge grant of exclusive rights to Novartis cancer drug, The Hindu Business line, Thursday, Nov, 13,2003. -

group and legal bodies forced the **Indian Controller of Patents and Designs to reject the application for patent by Novartis on Jan 25,2006**. It had been rejected on the ground that the product was a derivative of a known substance-Imatinib Mesylate and as per The Patents Act, any salt, polymorph or derivative of known substance is not patentable unless such salt, polymorph or other substance shows enhanced efficacy of the substance. From Jan 25, 2006, **the Indian Patents Office has terminated the exclusive marketing rights (EMRs) granted to the company on November 10, 2003 for Gleevac** on the same grounds as the above**.** Both the rejection by the Indian Patent Office and The Indian Controller of Patents and Designs gave a severe blow to this MNC-Novartis.

This Gleevac story gives us a key hole view of the status of India under the product patent regime.Product patents would give companies a mono poly of 20 years and it is really to be seen whether it leads to a shortage of ,or to a rise in prices of the medicines For instance, the cost of treatment for Gleevac would have gone up from Rs 12,000 to Rs 1.2 lakh a month had the patent been okayed. In Pakistan, prices reportedly shot up by 300 per cent when the patent regime was clamped in 2000. According to IMF economist Arvind Subramanian's 2004 report, which compares Malaysia and India, patents will push prices up by anywhere between 20 and 760 per cent. Novartis is the first instance where the Government has shown that it will ensure access to life saving drugs at affordable prices under the new regime.

The recent case of Natco Pharma launching its brand Bortenat (Bortezomib) 3.5 mg injection used in the treatment of multiple myeloma further strengthens our point regarding the difference in price of generic and branded drugs. Bortenat would be the first time launch of the Bortezomib generic in the world, besides being introduced in India for the first time. This adds another feather to Natco Pharma's cap after Imatinib Mesylate (launched under the brand name VEENAT). Natco has priced Bortenat at Rs 16,800 as compared with Rs 75,000 of the imported medicine.

Irrespective of the competition, because of the socio-welfare implication of the pharmaceutical prices, all over the world other than in the US, the prices of medicines are subject to government regulations. The Government of India has brought certain essential drugs under the price control. The price control along with the amendment of patent laws in early '70s resulted in a declining impact on prices leading to medicines becoming affordable to the common people. Based on India's own experience,as mentioned above in the Novartis' case and on a selective comparison of prices of a few drugs in countries where product patents is in force, it may be said that the stronger IPR protection would result in increase in the prices of the drugs and thus medicines will be inaccessible and unaffordable to common people.

One of the major advantages of the stronger regime is that, it would facilitate access to new medical products/new discoveries. Though there is a welfare loss associated with a probable price increase but there ought to be some welfare gain due to the introduction of new products in India by the MNCs, who presently don't find interest in introducing new drugs due to the weak protection. [*]It is observed that, though Pakistan also has process patent regime, some of the new drugs that were introduced in Pakistan by the MNCs were not introduced in India at all even though these MNCs were present in the country. This is because the MNCs feared about the competition from the counterfeit products in India,

[*] Sarkar Sudipta," Product Patent for the Indian Pharmaceutical Sector under the TRIPS regime"

whereas in Pakistan MNCs are stronger than the domestic firms.But it also argued that since the new patent regime would either raise the prices of new drugs to the international level or make the Indian population wait until the patent expires and drugs become cheaper, they in any case will be consuming old drugs, and the purpose of getting quicker access to new drugs will be defeated. So it may be said that actually prices would increase without much welfare gains in terms of access to new drugs.

It is also possible that higher prices charged by the MNCs may not really affect the consumers because; the research activities undertaken by the MNCs do not pertain to the requirement of developing and underdeveloped countries market .[9]Only 13 of 1373 new molecules developed during the last 30 years target diseases of tropical countries like India. Hence it can be said that the percentage of population affected by the price rise would be very less. Physicians can also play an important role by prescribing generic versions instead of the branded ones, thus helping the common people to get medicines at affordable rates.

The negative impact of product patents on prices can be attenuated to a considerable extent by the government. The two important instruments available with the government to regulate prices thereby protecting the consumers against exploitation through high prices are:

- To use flexibilities provided under TRIPS (for example **compulsory licensing, parallel imports**).
- To resort to price control, which is not forbidden under TRIPS.

The Government has already started focussing on price monitoring of essential drugs. This would serve to be a major relief to the pharmaceuticals industry.
The 14-member committee set up by Union Minister for Chemicals and Petrochemicals Ram Vilas Paswan have to study the cost of treatment per day of the 354 drugs listed in the national list of essential medicines (NLEM). And have to deduce whether the prices are high enough to warrant government intervention. The committee is also supposed to look at the disease profile outlined in the 10th Five-Year Plan to see which drugs a larger population is using. The Supreme Court had directed the government to ensure that drugs in the NLEM do not go outside price control.

The drug price control mechanisms prevalent in India are applicable on the patented drugs too. However,some economists have a different view altogether regarding the view that whether the DPCO(Drug Price Control Order) and price control have at all helped the pharmaceutical industry. They are of the view that absence of product patents messes up the pharmaceutical sector as it had encouraged piracy and production of sub-standard drugs in garages. To quote Dr. Bibek Debroy :

In judging success or failure of India's pharmaceutical policy, the criterion used for evaluation is, thus, important. If the number of producers is an indication, the policy was successful, the number of manufacturers having increased to 25,000. Since some of these drugs were sub-standard and didn't involve bearing fixed costs, prices were lower. (With competition and better enforcement of standards, the number of manufacturers has now dropped to around 9,000. And there is nothing wrong with this.) The effect of these policy-induced distortions was to discourage investments and innovation and encourage piracy, average R&D expenditure was less than 1 per cent of turnover. (As a result of allowing product patents, R&D expenditure has now increased to almost 10 per cent of turnover for larger Indian pharmaceutical companies and patents have been obtained, not only in India, but also in developed countries, the PCT having helped.) Companies

moved away from producing essential drugs to non-essential drugs (mainly because price control was exercised on essential drugs by the DPCO while non-essential drugs were left to market forces) Sometimes, they moved away from drugs to cosmetics and toiletries. Consequently, essential drugs had to be imported, a perverse instance of import-promoting industrialisation, probably the only country in the world to actually adopt such a strategy. Instead of research on drugs relevant for India-specific diseases, there was an obsession with cardio-vascular diseases, drugs for which could be pirated. The Indian pharmaceutical industry is now in a period of transition, no longer scared of intellectual property protection and in a position to tap India's strengths in human resources, science and technology. Policies still suffer from distortions, including restrictions on human and animal trials. [*]

Thus we see that this is a widely debated issue and we will be able to see the actual impact, only after a certain time gap.

7.1.1 New Drug Policy: boon to both patients and Industry

Chemicals and Fertiliser Minister Ram Vilas Paswan's acceptance of the pharmaceuticals industry's proposals vis-à-vis the new drug policy, if implemented, would pave way for an exciting future for the industry. At the same time, patients would benefit significantly from low-cost, high quality drugs as a result of competition in the industry.

After India became IPR compliant, most pharmaceuticals companies suffered heavily because of numerous ill-timed policies such as **MRP-based excise duty**, **constant reduction of drug prices by the NPPA, regulatory issues, patent-related legal battles and unmanageable R&D expenses.** Broadening the range of price control would have served as a disincentive for this sunrise sector. Research-based pharmaceuticals companies hope to be the biggest gainer as they can now focus significantly on researching India-specific diseases. The pharmaceuticals industry's offer is to cap generic-generics profits at 50 per cent of the cost.

The new policy would now consist of five main elements:

- There would be a public-private partnership to help poor families.
- Industry would offer drugs at concessional prices to government-run hospitals.
- The government, on its part, would promote competition to contain prices.
- The chemicals ministry would move from cost-based to a price-monitoring system.
- The ministry would set up a 14-member committee, including 11 members from the industry to work on the interim order of the Supreme Court.

Paswan has also announced a Rs 200-crore cancer rehabilitation fund to provide free/subsidised drugs. Price control will also be removed for all drugs priced up to Rs 3. In addition, he also agreed to push for increasing the healthcare budget from the existing 0.9 to 3 per cent of GDP.

Both the patients as well as Pharmaceuticals companies will get benefited. Patients can now get unbranded generics at rock-bottom prices and the pharmaceuticals companies will have full freedom in the R&D area. Cost-based price control is the last bastion of the dreaded licence raj. On paper, drug prices are controlled, but in reality, it puts a question mark on both the availability and quality of drugs. For instance, over 20 million Indian

[*] Debroy Bibek The Precedence Principle Business Standard, September, 07, 2006

women and 80 per cent of children suffer from anaemia. Similarly, thousands of flood-affected people suffer from Leptospirosis. Their sufferings are only further compounded due to non-availability of related drugs, due to their being placed under the price control system. By capping margins in generics, on one hand, and promoting R&D, on the other, the chemicals ministry is sure to kill many birds with one shot. [*]

7.2 Research and Development

Indian Pharmaceuticals Industry has basically been a hub for the generics. Consequently research has taken a back seat here . R&D was largely concentrated on process development for known bulk drugs although through novel and innovative process routes, invariably substituting for expensive imported raw materials enhancing the productivity and efficiency of the processes, besides research on formulations and known drug delivery systems. India's R&D forte has been in synthetic organic chemistry and process development. A few new drugs, using conventional screening techniques, have emerged from the Indian R&D, but none of them have been blockbusters.[*] But after 2005,reverse engineering skills will only be useful for manufacturing products going off patent. So Indian firms will be forced to go in for product-based research for achieving high profitability. Therefore Indian companies such as Ranbaxy,Dr. Reddy's laboratories ,Wockhardt, Sun Pharmaceuticals, and Cipla, among others have started to invest in product research as opposed to process research. There has been a shift from business-driven research to research-driven business. These firms are setting up labs for undertaking research on new molecules and are also continuing to hone their reverse engineering skills to manufacture drugs going off patent.

Investment in R&D by industry as a whole in India has been low, only around 0.6% of the turnover. In the Indian pharmaceutical industry the average R&D expenditure is around 2% of the turnover contributed by around 150 companies. The low investment in R&D is due to the low levels of profitability and comparatively small size of the companies. However, the scenario is now changing. Some pharmaceuticals companies now spend nearly 5% of their turnover on R&D. In addition to R&D in industry, substantial pharmaceuticals related R&D is carried out in publicly funded research organisations, mainly by the laboratories of Council of Scientific & Industrial Research (CSIR), Indian Council of Medical Research (ICMR), around 25 universities and a few pharmacy colleges. Some of the new R&D units in industry and a few of the publicly funded laboratories are equipped with sophisticated laboratory equipment, instruments and pilot plant facilities. The R&D manpower is generally highly qualified and proficient in conventional techniques of pharmaceutical R&D.

But Generic Industries will experience a good future as $72-billion worth drugs expected to go off patent (between 2006 and 2010). This implies a great boost for the generics industry. To **maximize** profits from their technological expertise, many generic companies make it a top priority to be the first to file a generic version with patent challenges so that they can enjoy the six-month marketing exclusivity. This strategy can bring massive revenues in the short term

To support developments and research of this kind, the Indian government is providing a range of tax concessions designed to encourage R&D, including a 10-year tax holiday on income arising from R&D. Besides, planning commission earmarked $34 million towards drug industry R&D promotion fund for the tenth plan. Moreover, the series of proposed

[*] Sikka S Harinder, A win-win drug policy, Business Standard, New Delhi August 23, 2006,
[*] PRDC Report

recommendations of the A.R. Mashelkar committee set up by the government regarding price liberalization, fiscal incentives and appropriate R&D regulatory framework, would be expeditiously implemented to give an impetus to R&D activities. The aim is to at least double the domestic pharmaceutical industry's level of R&D expenditure - which is very low by international standards - by 2005. After 2005, there will be wide scope for Indian drug companies in the world market, and those that have strong R&D activities as well as significant domestic and international business will have an edge over others

The year 1994-95 was the turning point for the industry due to the advent of the WTO. The industry has since sought to reorient itself from looking inwards to being a player in the global arena. The increased proportion of R&D expenditure to both investment and turnover reflects the thrust on R&D by the Indian pharmaceutical industry.

Table 6: Expenditure incurred by the Indian firms in R&D of New Drugs

COMPANY	R&D Expdt. In Rs.million 2003-04	%Age of total turnover, 2003-04	R&D Expdt. In Rs.million 2002-03	%Age of total turnover, 2002-03	R&D Expdt. In US$ million, 2003-04
Ranbaxy Laboratories	2761	7.80	1922	6.80	60
Dr.Reddy's laboratories	2261	12.99	1635	9.92	49
Sun Pharmaceuticals	1077	10.20	658	7.70	23
Cadila Healthcare	882	7.52	383	3.72	19
Wochhardt	604	7.89	462	6.23	13
Nicholas Piramal India	559	3.90	185	1.63	12
Lupin	460	3.90	360	3.49	10
Torrent Pharmaceuticals	397	8.90	312	6.98	9
Orchid Chemicals & Pharmaceuticals	397	5.56	278	5.13	9
Glenmark pharmaceuticals	372	9.67	306	9.16	8
Dabur Pharmaceuticals	182	8.50	175	1.42	4
J B Chemicals & Pharmaceuticals	69	2.20	50	1.73	2
Total	10,021	7.73	6726	5.55	218

Source- Chaudhuri Sudip (2005) table 5.2, pg 161,

Table 7:R&D Expenditure of Indian Pharmaceutical Companies from 1981-97 to 2005-06:

Year	(Rs. Crores)
1981-97	14.75

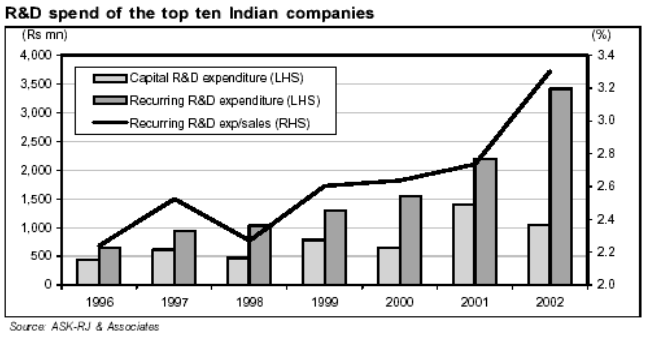
1997-98	220.00
1998-99	260.00
2001-2002	320.00
2005-2006	530.00

Source- pharmainfo.net

This table depicts that over the years there has been an upsurge in the R&D Expenditure.

Graph-1[*]

Increasing R&D Expenditure 1996-2002



www.ibef.org March 2005

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[*] www.ibef.org

Table 8
Expenditures by top Pharmaceutical MNCs ,2003

MNC	R&D Expenditure,US $ billion	R&D Expenditure as per cent of sales
Pfizer	7.13	17.99
GlaxoSmithKline	4.54	15.23
Merck	3.17	9.47
Johnson&Johnson	4.68	24
Aventis	3.23	17.01
AstraZeneca	3.45	18.30
Novartis	3.07	19.16
Bristol-Myers Squibb	2.27	15.21
Wyeth	2.09	16.56
Eli Lily	2.35	18.68
Total	35.98	16.63

Source- Chaudhuri Sudip (2005) table 5.4 page 167

The comparison of the two tables (table 6 and table 8) above clearly indicates the paucity of funds at the disposal of the Indian Pharmaceuticals companies. The tenth largest MNC Eli Lily spent US$2.35 billion as compared to the largest in India, Ranbaxy that spent at around US$ 60 million. Thus, we see, India poorly compares with the pharmaceuticals giants worldwide in terms of R&D Expenditure incurred. To raise resources R&D Firms may consider a variety of options like mergers with other Indian Firms, collaboration with foreign firms, joint ventures with foreign firms in other countries, leveraging the low cost home base ,joining R&D consortia centered around Institutes like CDRI, Lucknow or IICT and joining industry oriented research organizations sharing expensive facilities.

One of the advantages of the new patent regime is the Bolar Provision (discussed earlier), which entails a free flow of technical knowhow and knowledge giving a tremendous boost to local companies to invest in research. The higher cost of the R&D serves to be an effective entry barrier for new firms and hence only firms with large flow of funds are capable of any inventive activity. In developing countries, a handful of firms have sophisticated R&D facilities and others benefit mainly from the spillovers of the resultant R&D. More often small firms shy away from investing in R&D because; financial risk involved is too high as there are more possibilities of failure than success.

For instance, cost of developing one new drug in the US increased from $54 million in 1970 to $231 million in 1990. Recent studies indicate that 1 out of 5000 compounds synthesized during applied research eventually reaches the market. Other estimates indicate that of 100 drugs that enter the clinical testing phase I, about 70 complete phase I, 33 complete phase II, and 25-30 clear phase III. Only two-thirds of the drugs that enter phase III is ultimately marketed. According to a US FDA report 84 per cent of new drugs placed on the market by large US firms during the period 1981-88 had little or no potential therapeutic gain over existing drug therapies. Similarly in a study of 775 New Chemical Entities introduced in to the world during the period 1975-89, only 95 were rated to be truly innovative. [*]

[*] Sarkar Sudipta," Product Patent for the Indian Pharmaceutical Sector under the TRIPS regime"

Because of these reasons and due to the protected policy regime, the R&D investment in India has been very low and started picking up only in the mid '90s, when TRIPS came into effect. . The Indian pharmaceuticals R&D pipeline has been evolving over the years. The pipeline is in the early stages and is likely to take two to three years to reach critical mass. Of the Rs.1, 800 crores spent on R&D in 1998, 35 per cent belongs to the public and joint sector and that of the private sector is about 65 per cent. In spite of the growing investment in R&D, R&D as percentage of sales ratio stagnates around 2 per cent. Further of the 1261 Department of Science and Technology recognised R&D units, 256 have spent more than Rs. 1 crore every year. 350 have spent between Rs.25 lakhs and Rs. 1 crore and the remaining below Rs. 25 lakhs.[**] This clearly indicates that most of the R&D investment was perhaps directed towards **process improvements** and adapting the technology to local conditions thus resulting in technology spillovers rather than in new product developments. For instance, the UK multinational Glaxo was faced with several local competitors on the first day when its subsidiary marketed its proprietary drug Ranitidine in India, because the competitors enabled by the weaker patent regime were ready with the indigenous version of Ranitidine.

Table 9
Drug discovery pipeline of Indian pharmaceuticals companies

NAME OF COMPANY	PRE CLINICAL	PHASE 1	PHASE 2	PHASE 3
Ranbaxy	5	3	2	n.a.
Dr. Reddy's laboratories	5	2	1	n.a.
Wockhardt	n.a.	n.a.	1	n.a.
Nicholas Piramal	n.a.	n.a.	1	n.a.
Lupin	n.a.	n.a.	2	n.a.
Orchid	2	1	n.a.	n.a.
Torrent	19	n.a.	n.a.	n.a.
Glenmark	1	1	n.a.	n.a.
Dabur	29	1	1	n.a.
Total	64	12	4	0

Source-www.ibef.org
n.a-not available

The positive sides of undertaking research in India are R&D costs in India are much less than that in the developed world and both New Drug Discovery Research and New Drug Delivery Systems programmes can be market conducted at very competitive rates. India also has a well-established network of research labs and a strong pool of skilled scientific personnel. The success of a few companies in this area (table shown below) has also demonstrated to the rest of the industry that investments in R&D can yield handsome returns. The Investigational New Drug stage may cost $100 to 150 million overseas but costs only around Rs.40 to 60 crores in India, says the Mashelkar Committee report. The report adds that while clinical trials cost approximately $300 to 350 million abroad, they cost about Rs.100 crore in India.

[**] Sarkar Sudipta," Product Patent for the Indian Pharmaceutical Sector under the TRIPS regime"

On the negative side, R&D activities in India are adversely impacted by lack of financial resources which compels them to focus mainly on drug delivery systems and similar molecules; inadequate regulatory framework which relates to a host of issues such as lab-testing of animals; outdated and inadequate patent office; long delays in getting required approvals for conducting trials etc. Yet, to stay competitive in the future (i.e. post TRIPS), the companies will have to increasingly refocus and invest heavily in R&D.

Most Indian companies realize that it will be difficult for them to commercialize their discoveries on an international basis on their own as they are unable to perform a start to finish model in NCE research, due to scarcity of skills and required funds: says Annual Report, 2001-02 of Glenmark Pharmaceuticals . Therefore they are entering into **licensing deals** i.e., to develop new molecules and license out the molecules to the MNCs in the early phase of clinical development and strategic alliances with international companies. Dr. Reddy's Laboratories initiated this licensing out of new molecules. Ranbaxy, Torrent and Glenmark had followed suit.

India's inherent strengths (low-cost manufacturing, strong re-engineering skills, talented human resource at low cost) makes it a **lucrative outsourcing destination** for global players and also helps to tap international markets through **contract manufacturing** and **conducting collaborative research**. An alliance with an Indian firm is expected to aid innovator companies to capitalise on the low-cost base for collaborative and contract research and manufacturing, while generic players will benefit by enhancing their first-to-file position, expanding their portfolio and reducing their costs. Although the outsourcing of the drug discovery process is gradually gaining momentum, research-outsourcing demand in India will come chiefly from conducting/supporting clinical trials. The availability of a large patient population (in that, they have not undergone treatment) and well trained medical professionals at significantly low costs has made India an attractive destination for conducting global clinical trials. At present, 90 per cent of the trials conducted in India are bio-equivalence studies for filing abbreviated new drug applications (ANDA) with the US FDA. Only 10 per cent of the studies are actual clinical trials aimed at the development of NMEs. However, this ratio is expected to change in favour of clinical trials for NMEs by 2009.
Some deals finalised for clinical trials are listed below:
• Eli Lilly has 17 clinical research projects in 40 hospitals across India.
• Pfizer has picked 6 cities in northeast India for clinical trials for an anti-malaria drug.
• Roche has set up clinical trial sites for lung cancer drugs in India.[*]

Table 10
Out licensing deals finalised to date

Company	MNC Player	Therapeutic category	Size of Deal	Received	Compound	Year	Status
Ranbaxy	Schwarz Pharma	BPH	$32 million	$10.3 million	BPH Compound	2003	Discontinued
Dr. Reddy's Laboratories	Novo Nordisk	n.a	n.a	n.a	Ragaglitzar	1998	Discontinued
	Novo Nordisk	Diabetes	$17 million	$10.5 million	Balaglitozone	1997	Discontinued

[*] CRIS INFAC

	Novartis	Diabetes	$55 million	$55 million	DRF 4158	2001	Discontinued
Glenmark	Forrest Labs	Respiratory	$190 million	$10 million	Anti Asthma	2004	In Progress
Torrent Pharma	Novartis	CVS	$3.7 million	$0.6 million	Age Breaker	2004	In Progress

Source: CRIS INFAC
n.a-not available

India was estimated to account for around 7 per cent of the global outsourcing market for bulk drugs in 2004-05.By 2009-10, India is expected to account for 10-15 per cent of the global bulk drug outsourcing market, which is expected to surge at a compounded rate of 22.2 per cent, from Rs 80.7 billion ($1.8 billion) in 2004-05 to Rs 220.1 billion ($4.9 billion) in 2009-10. However, on the domestic front, outsourcing demand for bulk drugs is expected to slow down in the short-to medium term after which demand (as a percentage of apparent domestic consumption of formulations) is expected to pick up marginally to show an overall growth of 1.6 per cent between 2004-05 and 2009-10 to Rs 12.2 billion. The overall bulk drug market is expected to surge at a compounded rate of 20.4 per cent to Rs 232 billion in 2009-10.[**]

Table 11: Overall bulk drug demand outlook

	2000-01	**2004-05 (E)**	**2009-10 (P)**	**CAGR (2004-05 to 2009-10)**
Domestic outsourcing	6,045	11,289	12,221	1.6
Exports/Contract manufacturing	39,285	80,664	220,091	22.2
Total market	**45,330**	**91,953**	**232,312**	**20.4**
E: Estimated; P: Projected				

Source: CRIS INFAC

This way their development costs will get shared and returns will accrue faster. Yet, there is another part to this story, which is a case of worry. This policy of licensing out may shift the focus of research in the LDCs as major R&D firms may be more involved in drug discovery that addresses the global diseases and neglect the research that is more relevant for the LDCs. In this context the words of Amit Sen Gupta, of the National Working Group on Patent Laws, is worth adding: ***"I think for me it's frightening that ten or twelve people today are deciding what are the kind of drugs that need to be researched because clearly those drugs are being researched not because of the health needs but based on how much profits they can bring in. That's why you have research money going into drugs for baldness or Viagra but the last drug for tuberculosis was 30 years back. When you deny people cars or washing machines they don't die, when you deny people drugs they die and they die in millions."***

It is apparent that Indian pharmaceutical R&D has several scientific-techno-economic advantages that by far outweigh the few inherent weaknesses. The opportunities are appealing and attractive and the threats manageable. Thus if the proper policy support

[**] CRIS INFAC

and direction is given, the industry can carve out a niche for itself in the global market place.

7.3 Investment Strategies

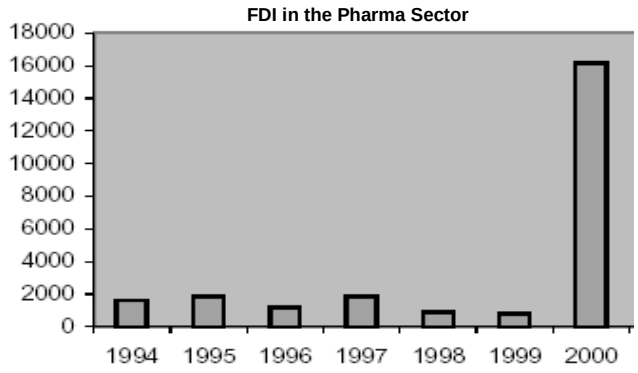
7.3.1Foreign Direct Investment (FDI):

Foreign Direct Investment creates a long-standing association and commitment of one economy over the other.The weak protection of the IPRs in the Pharmaceutical sector in India served as a disincentive for FDI mainly by the countries like US,Japan and Germany. However, with the change in scenario, that is post TRIPS, there has been an increase in FDI.

This graph below shows the FDI in the pharmaceuticals sector from the year 1996-2000.It shows a steady increase.

Graph-2

FDI in the Pharmaceutical Sector from 1996 - 2000



www.ibef.org March 2005

If the IPR is strengthened, it will lead to an increase in foreign direct investment (FDI) in R&D, direct manufacturing or joint ventures. However, this inference cannot be definitely concluded since IPR is only one of the factors in attracting FDI. FDI flows depend on skills availability, technology status, R&D capacity, enterprise level competence and institutional and other supporting technological infrastructure. According to US Under Secretary of Commerce for International Trade Franklin L Lavin *"India's FDI policy should be more flexible to allow more foreign equity and ensure level-playing field for foreign and domestic companies,"* Highlighting the FDI flows to countries with allegedly low levels of IPR protection, Correa observes that the perceived inadequacies of intellectual property protection did not hinder FDI inflows in global terms. Thus FDI increased substantially in Brazil since 1970 until the debt crisis exploded

[*] www.ibef.org

in 1985, while in Thailand FDI boomed during the eighties. In contrast developing countries that had adopted stronger protection have not received significant FDI inflows. He further observes that FDI in the pharmaceutical industry outpaced FDI in most other sectors in Brazil after patent protection for medicines was abolished in that country. In Italy after the introduction of process patent protection in 1978, FDI increased.[*] Hence, it appears that patent production does not have significant impact on FDI.

From August 1991 to May 2006, FDI inflows received are to the tune of Rs. 43217.70, amounting to $1009.63 and constitute 3.07% of the total FDI inflows in the country.[**]

Table-12: FDI inflow into pharmaceutical sector from 2002-03 to 2006-07 (Rs. In crore and $ in millions in brackets:

Sector	**2002 – 03 (April – March)**	**2003– 04 (April – March)**	**2004– 05 (April – March)**	**2005 – 06 (April– Jan)**	**2006-07 (April-May 06)**	**Cumulative Inflows (Aug'91-May'06)**
Pharmaceuticals	192 **(40)**	502 **(109)**	1,343 **(292)**	760 **(172)**	10 (2)	4,322 **(1010)**

Source-Dept. of Industrial Policy and Promotion

Though India is taking a well set of measures to improve the flow of FDI it is not able to wipe the ambiguity in the minds of investors. According to Boston Consultancy Group (BCG), FDI investors perceive a high degree of uncertainty in India. This includes political and administrative uncertainty, legal delays and bureaucratic delays. The positive image of India needs to be improved.

TRIPS had led us to believe that Patent protection in India will stimulate investment into R&D that will benefit Indian consumers and will reward India with increased foreign investment**.** But in reality Profits generated by sales in India will not be large enough to affect the R&D agenda of multinational pharmaceutical companies. A recent case study estimates the returns to the pharmaceutical industry after implementation of a product patent regime in India to be only $53 million per year. According to the recent findings of an international commission, ***"Integrating Intellectual Property Rights and Development Policy." Final Report of the UK Commission on Intellectual Property Rights. September 2002."*** *"The evidence suggests that the IP system hardly plays any role in stimulating research on diseases particularly prevalent in developing countries, except for those diseases where there is also a substantial market in the developed world, Nor it is likely that the globalization of IP protection will lead to greater investment by the private sector for the development of treatments for diseases that primarily affect developing countries."*

The bad news for India is that 90% of pharmaceutical executives, from North America, Europe, Asia and India have voted for China over India (survey by Bain and Company) for low –cost drug manufacturing. Regarding the factors affecting the Pharmaceuticals

[*] Sarkar Sudipta," Product Patent for the Indian Pharmaceutical Sector under the TRIPS regime"

[**] Source: Department of Industrial Policy and Promotion

Industry in India, 56% have voted for the IPRs, 52% for parallel trade or grey market imports and 46%, the regulatory uncertainty. But, the brighter side of the survey is that India has been foreseen to be much better five years from now. Indian market has also been characterized as attractive by 35% as in 2006 and 58% expect it to be attractive by 2011.[*]

Bain has recommended that *Indian Pharma companies should strive for low cost leadership in their core generic drug businesses through a rigorous focus on operating efficiency and begin to invest in innovation.The Indian government should create the right business environment for both MNcs and Indian companies by addressing key concerns over IP protection, parallel trade and regulatory uncertainty.MNCs should start investing now to take advantage of the domestic Indian market but it should be done in a measured way while pressing for regulatory reforms.*

7.3.2 Mergers and Acquisitions:

The health-care costs are rising worldwide. Leading companies are merging. Strategic alliances and collaborations are taking place in order to meet the increasing R&D budgetary requirement that exceeds a billion dollars each for many leading global pharmaceuticals players As for India, The generic nature enables the pharmaceutical companies to enjoy a cost advantage, thus encouraging them to acquire firms abroad. These industries are enjoying the foreign face, which some times helps them to acquire some other firms and also benefit with brand equity.

The increasing number of local pharmaceuticals multinationals points to India's strong foothold at a global level. The number has gone up to 12 in 2004-05 and 2005-06 owing to rising global buyouts and organic expansion. The new entrants are Dr Reddy's Laboratories, Wockhardt, Nicholas Piramal, Sun Pharmaceuticals, Glenmark, Orchid Chemicals and Pharmaceuticals, Unichem, Torrent Pharmaceuticals, Cadila Healthcare, Lupin and Cadila Pharma. The drug sector had only one Indian multinational, Ranbaxy Laboratories, till 2004.[*]

Table-13
Pharmaceutical companies and their subsidiaries

Rank	Company Name	Subsidiaries in Number of countries (global subsidiaries)
1	Ranbaxy Laboratories	25
2	Dr. Reddy's Laboratories	10
3	Sun pharmaceuticals	8
4	Wockhardt	7

Source-Business Standard,Aug 24, 2006

On the M&A front, the year 2005 had been quite significant for the domestic pharmaceutical sector. Although, most of the overseas subsidiaries were set up through global expansions, the number of global acquisitions has also increased substantially in the last two to three years. Since the Indian companies have adopted new strategy of

[*] China preferred choice for Pharma cos.-study, The Hindu,,Aug 06,2006
[*] Unnikrishnan H C,Local pharma players storm multinational bastion , Business Standard August 24, 2006-

acquiring medium and small companies overseas, the estimate worth of global acquisitions in the last three years is more than Rs 4,500 crore.

Table-14
Mergers and acquisitions by Indian Pharmaceutical Companies on a global level

Name of Company & country	Acquirer	Type	Total Value (in $ million)	Year of acquisition
Betapharm, Germany	Dr. Reddy's Laboratories	Acquisition	480	2005
Terapia, Romania	Dr. Reddy's Laboratories	Buyout	324	2005
Docpharma, Belgium	Matrix	Acquisition	263	2005
Pfizer unit, Europe	Nicholas Piramal	Acquisition	50	2005
Avecia Pharma	Nicholas Piramal	Acquisition	16.25	2005
RPG Aventis	Ranbaxy	Buyout	80	2005
Mexican API unit of Roche	DRL	Buyout	59	2005
Carbogen Amcis AG	Dishman Pharma Solutions (DPS AG)	Acquisition	75	2006
CP Pharmaceuticals (UK)	Wockhardt	Acquisition	18	n.a
Milpharm Ltd., UK	Aurobindo pharmaceuticals Ltd (APL)	Acquisition	60	2006
GSK generic drug unit in Spain	Ranbaxy	Acquisition	undisclosed	2006
Manchester based contract research company	Dishman	Acquisition	Not known	2005
IO3S Switzerland	Dishman	Acquisition	Not known	2006

Source-Business Standard, August 24,2006 and compiled data from various websites
n.a-not available

Analysts expect the M&A activity to intensify, as the consolidation will play a crucial role in future. The size and economic scale does matter in the highly competitive environment. During the last two years, major acquisitions were engaged in marketing, but some domestic companies had invested in building manufacturing capacities in developed markets. Indian companies have already installed plants in the US, Europe, Brazil, Russia and China. Analysts pointed out that the medium scale domestic companies will first strengthen their marketing activity in these countries and then they

will set up manufacturing units to improve the supply chain. At the same time, the companies are also setting up capacities in the domestic locations to explore the generic boom.

The domestic pharmaceutical companies have created their brand image in the regulated markets, which is evident form the success of the fund raising initiatives through securities and commercial papers. Several companies issued foreign currency convertible bonds to part-finance their expansion and acquisitions. With strong financials, those issues received overwhelming response from foreign investors.

8. Future of The Pharmaceutical Industry in India

The strength of the Indian pharmaceutical industry is in reverse engineering. Such units by utilising the provisions under **compulsory licensing, parallel imports** and exceptions to **exclusive marketing rights** under the TRIPS agreement should aim at producing the generic version of the patented product and those that are nearing patent expiry. Such firms should also be engaged in research leading to new drug delivery mechanisms and in identifying new uses of existing drugs. In this context, it is also essential to protect the innovations that have been introduced by the technology spillovers. Further more, some of the new sources of NCEs could be plants, microbes, fungi, insects and various venoms. The extracts from these material sources must continue to form a major source of entirely novel structures.

It is true that the New WTO regime has stimulated the R&D investment in India, but it is equally true that even the largest Indian companies are no match for the pharmaceutical giants in the world in terms of size, scale of operation and R&D budgets as of now and it will require some more years to make it big in the field of new drug discoveries. Some of the big units have started strengthening their R&D (as mentioned above) and have also filed number of applications for DMFs (drug master files). Companies such as Ranbaxy Laboratories, Nicholas Piramal, Cipla, Glenmark Pharma and many others have been ramping up their R&D programmes in a big way and plan to increase their R&D expenditure to 7-10 per cent of the sales revenues from the present industry average of 2-3 per cent Yet, India can harness certain other opportunities available to it right now. Enlisted are some of the ways that can help India to have a considerable impact in the global arena:

a) **Most cost-effective manufacturers of generic drugs.** The global market for generic drugs in 2005 is estimated at $36 billion and should grow further with the impending expiry of patents on drug sales worth over $50 billion.
b) **Outsourcing of R&D and manufacturing**. (Discussed in detail above)
c) Investment on manufacturing and production capacities (specially foreign approved ones).
d) Economising on scarce R&D resources by going in for mergers and consolidation.
e) To rectify the bottlenecks contributing to the widening gap between the proposed FDI and the actual FDI.
f) To figure out where the Indian firms are lacking by observing the difference between the number of patents filed and the patents granted.
g) The governing body may define a list of essential medicines, such as antiretroviral (ARV) agents, that would be subject to somewhat more relaxed patent protection compared to other drugs.

h) Internal networking and co-ordination amongst different constituents of innovation chain to bring down the time and costs of new drug discovery and its introduction in the market place.

In this respect, the SWOT Analysis (Strengths, Weaknesses, Opportunities, Threats) of the Indian Pharmaceuticals Industry is worth mentioning. The analysis points out to India's prospect to come out as a global player:

Table 15: SWOT Analysis

STRENGTHS	**OPPURTUNITIES**
Strong manufacturing base	Outsourcing and networking.
Rich base of traditional knowledge	Potential for clinical research and initiating clinical trials.
Well developed engineering base	Contract manufacturing arrangements with MNCs
Experience in successful process development	Potential for developing India as a centre for international clinical trials
Access to pool of highly trained manpower with low costs.	Significant export potential.
WEAKNESS	**THREATS**
Low investments in innovative R&D due to paucity of resources.	Inability to cope-up with the rapidly changing new drug discovery technologies and processes at the global level
Lack of strong linkages between industry and academia	Product patent regime poses serious challenge to domestic industry unless it invests in research and development
Lack of resources to compete with MNCs for New Drug Discovery, Research and commercialization of molecules on a worldwide basis.	R&D efforts of Indian pharmaceutical companies hampered by lack of enabling regulatory requirement.
Inadequate regulatory standards.	Export effort hampered by procedural hurdles in India as well as non-tariff barriers imposed abroad
Inadequate trained manpower in emerging areas.	Lowering of Tariff Protection.

Source-PRDC Report

The three tropical diseases or rather the diseases prevailing mostly in the developing countries-AIDS, Tuberculosis and Malaria will be giving Indian Pharmaceuticals a $2 billion opportunity each year. WHO, UNO to fight these diseases, is pooling funds worth $4 billion yearly till 2015. As a result, campaigns like Global Fund for AIDS, TB and Malaria, President Bush's Emergency Plan for AIDS Relief (PEPFAR), Stop TB Partnership and Roll Back Malaria are being affected. Indian Companies stands to benefit as they are in a position to capture 50% of the market owing to their cost advantage, expertise in anti-infectives segment and experience in procuring regulatory approvals. Moreover, India having the highest number of USFDA approved plants outside USA and having the same disease pattern gives them an edge over their US and European counterparts in generics (anti-retrovirals for AIDS and anti-infectives for treating TB and malaria — are roughly 20 to 30 per cent cheaper to the generic drugs supplied by the US

and European companies). It is predicted that all the companies who are in this anti infectives segment would join the bandwagon of suppliers for such sponsored products. The total burden of these three diseases is $23 billion annually (including prevention, diagnosis, treatment and care), as estimated by various global agencies. During 2006-2010 period, AIDS programmes alone would receive funds worth $3 billion, tuberculosis about $450 million and malaria another $768 million, each year. Roughly 50 per cent of it could accrue to India. [*]The challenges before the Indian company now is to make investments in procuring WHO approvals, attain efficiencies in supply chain management to ensure timely delivery of drugs as well as maintain the cost advantage.

The Human Development Report of 1999 has highlighted that there is a tremendous concern about the control of knowledge as tighter intellectual property rights raise price of technology transfer and increase the technological gap and block the developing countries out of dynamic knowledge sector. On the other hand, the major pharmaceutical companies argue that compliance of the provisions of TRIPS would stimulate transfer of technology, encourage foreign direct investment, strengthen R&D investment and also ensure early introduction of new products in developing countries. These arguments are invariably backed by data on increased FDI in some countries where stringent IPRs were introduced. Whereas these claims and counter claims could be debated, the Indian model has to be based on providing medicines at affordable prices to the needy Indian population on one hand and also leveraging the Indian intellectual prowess on the other, through which India could create its own intellectual property.

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